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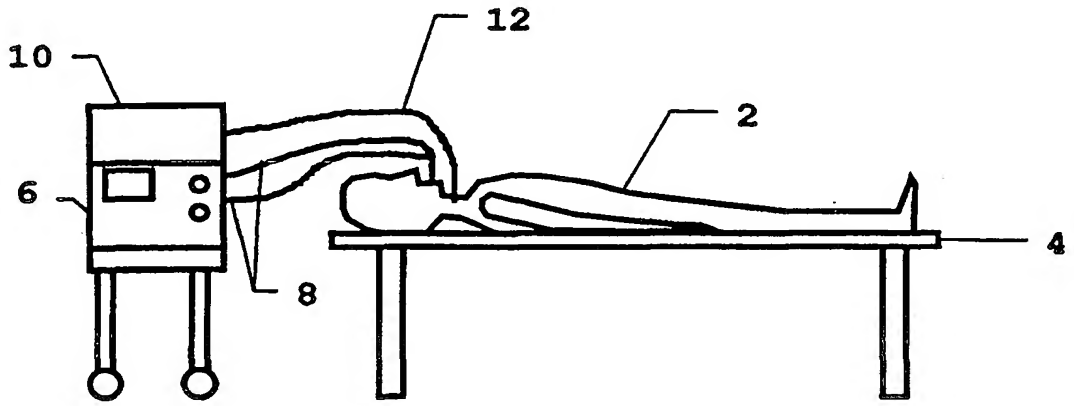
(54) Title: RESPIRATORY AID SYSTEM WITH RESPIRATION DETECTOR, PICKING UP NEUROELECTRICAL SIGNALS



(57) Abstract

A respiratory aid system (6, 10), comprising a device (6) arranged for connection to a living creature (2) in order to facilitate, support and/or control the respiration of the living creature (2), is described. Such devices (6) can consist of e.g. ventilators and neuroelectrical stimulation devices. Faster, more efficient and more accurate respiratory aid can be given when the system (6, 10) contains a respiration detector (10), devised to pick up neuroelectrical signals from the living creature (2), identify respiration-related signals and send a control signal, related to the identified signals, to the device (6).

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Description

RESPIRATORY AID SYSTEM WITH RESPIRATION DETECTOR, PICKING UP NEUROELECTRICAL SIGNALS

The present invention relates to a respiratory aid system according to the preamble to claim 1.

The present invention also relates to a respiratory aid system according to the preamble to claim 10.

The present invention also relates to a respiration detector according to the preamble of claim 13.

The present invention further relates to a method for identifying physiological attempts at respiration according to the preamble of claim 14.

Disease and injuries can make it necessary for a patient to receive respiratory aid. In principle, this respiratory aid can cover everything from facilitating a patient's spontaneous breathing to complete control of the patient's breathing. All is depending on the nature and scope of the disease/injury and the patient's treatment needs. Patients receiving anaesthesia (regardless of whether it is supplied because of disease/injury, for cosmetic surgery or for some other reason) may also need respiratory aid.

It should be noted that "patient" in this context relates to both people and animals.

Today, the most common way of providing respiratory aid is with ventilators (respirators) delivering a pressurised gas to the lungs. A number of ventilation modes are known, depending on which respiratory aid to supply. See for instance the article "Mechanical Ventilation", Chest 1993; 104; 1833-1859, which includes a discussion relating to

objectives and recommendations regarding mechanical ventilation.

Another way to provide respiratory aid is to apply extracorporeal pressure around the entire thorax and midriff (e.g. the classic 'iron lung' used for e.g. patients whose respiratory muscles have been damaged by polio). A device of this kind is disclosed in US Patent No. 5,222,478.

Another way to induce breathing is by means of electrical stimulation. Either by direct stimulation of the muscles of the diaphragm in particular or by indirect stimulation via the nervous system, in particular the phrenic nerve. A diaphragmatic pacer is disclosed in US Patent No. 5,056,519. A nerve stimulator for treatment of respiratory disorders is disclosed in PCT publication WO 93/01862.

Stimulation of the respiratory system can also be made magnetically, as disclosed in US Patent No. 5,857,957.

One problem shared by all respiratory aid is to obtain information on when the patient needs to breathe and how much the patient needs to breathe. This is particularly the case for completely controlled respiratory aid with mechanical ventilation.

In completely controlled respiratory aid the physician bears the main responsibility for programming appropriate respiration parameters, such as respiratory rate, tidal volume, inspiration duration etc.

Measurement of physical parameters related to metabolism, such as oxygenation of blood, the carbon dioxide content of blood etc can be of help for the physician when programming the respiration parameters. Some of the physical parameters can be estimated from accurate analysis of the contents of

expired gas. The measurements of physiological are too rough to provide enough information for individual breath to breath control but can supply important information for the overall regulation of respiratory rate etc.

For patients that can breath spontaneously, at least in part, information of the patients breathing can be determined. When pressure, flow and/or changes in temperature inside or outside the patient's airways are sensed, the patient's spontaneous attempts to breathe can be detected and used for triggering the respiratory aid. The magnitude of each attempt to breathe can also be determined and used to affect the magnitude or type of respiratory aid. This option is mainly useful in supported respiration aid.

One problem in supported respiration aid is that the patient's spontaneous attempts of breathing come in conflict with the supportive respiration aid. This is normally referred to as competition. One way of avoiding competition is to sedate the patient and use completely controlled respiratory aid only.

The above mentioned physical parameters can of course also be used for spontaneously breathing patients for determining when a patient needs to breathe.

Lung movements can also be measured by measuring the impedance across the chest (and lungs). Lung movements are also indicative of attempts to breathe.

Direct measurement of the musculature participating in respiration can also provide information relating to attempts to breathe.

Common to all these procedures is the circumstance that none of them provide an accurate physiological picture of the patient's true respiratory needs.

Breathing is part of the body's autonomic system. One important known factor affecting this autonomic system is the body's own chemical receptors that sense carbon dioxide content. But the autonomic system is also affected by a number of other physiological factors. Some of these factors are probably still unknown to the medical expertise.

One objective of the invention is to achieve a respiratory aid system designed for determining, more reliably and efficiently than in earlier systems, when a patient wishes to or needs to breathe.

Another objective of the invention is to achieve a respiration detector capable of more rapid and efficient sensing than hitherto of a patient's attempts at breathing.

Yet another object of the invention is to achieve a method for identifying physiological attempts to breathe.

The first objective is achieved according to the invention when the respiratory aid system is devised as is evident from the characterising part to claim 1.

Advantageous improvements and embodiments of the respiratory aid system according to the invention are evident from the dependent claims to claim 1.

A patient's true respiratory need can be established by registering neuroelectrical signals and extracting the signal components related to respiration. In other words, the nerve impulses are detected and used to extract information. The nerve impulses contain information about a patient's

respiratory needs that automatically comprises all physiological functions with an impact on respiration. True respiratory needs can be utilised for controlling a device supplying respiratory aid. In particular, the point in time for each individual breath (initiated by the patient) can then be determined from the neurological signals, but these signals also contain about all the information essential to individual breaths.

In principle, all kinds of known apparatuses for respiratory aid, such as ventilators, anaesthetic machines, nerve stimulators, muscle stimulators and magnetic stimulators, can be used, where or when appropriate with regard to the conditions in each specific case.

Neuroelectrical signals (nerve impulses) related to respiration originate in the respiratory centre of the medulla oblongata, and these signals can, in principle, be collected from the respiratory centre or picked up along the nerves carrying the signals to the respiratory musculature. The phrenic nerve has proved to be particularly suitable for use as a result of its location. Signals can be picked up with extracorporeal sensor means placed on the skin, with needle-shaped sensor means adapted to puncture the skin to get close to (or in contact with) the nerve or with sensor means designed to be placed on a surgically exposed nerve. Implanted sensor means could also be considered, in particular for long-term treatment.

One version of the respiratory aid system utilises sensor signals related to breathing for triggering an inspiration by the patient. The triggering can be adapted so inspiration occurs at a phase in which the patient would have breathed spontaneously. In completely controlled respiratory aid, this would provide a patient-related respiratory rate. In supported respiration, this would also lead to a much faster

response to the delivery of respiratory assistance than in prior art technology. Competition between the patient and the ventilator can be avoided.

In cases in which the patient has a varying capacity or ability to breathe spontaneously, a respiratory sensor can be used for determining whether a respiratory signal from the respiratory centre really leads to a spontaneous inspiration or an attempt at inspiration. This kind of respiratory sensor can also be used for determining the strength of an inspiration/attempt at inspiration.

If a spontaneous inspiration does occur, triggering is not always necessary and can be completely inhibited in some instances. The respiratory aid system could instead be devised to provide supplementary support (possibly according to information derived from the neurological signals) for a spontaneous inspiration when the latter is inadequate. For example, the patient's respiratory musculature might be too weak to sustain physiological inspiration duration.

The first objective is also achieved, according to the invention, when the respiratory aid system is devised as is evident from the characterising part of claim 10.

Advantageous improvements and embodiments of the respiratory aid system according to the invention are evident from the dependent claims of claim 10.

With a respiration detector for sensing the respiration-related part of the patient's nervous system, attempts at respiration can be detected at the earliest possible stage and used for controlling a device for supplying respiratory aid.

The second and third objectives are achieved according to the invention with a respiration detector according to the characterising part of claim 13 and a method according to the characterising part of claim 14.

In principle, the respiration detector can be designed as described above in conjunction with the description of the respiratory aid system according to claim 1.

The respiratory aid system and respiration detector according to the invention are described below in greater detail, referring to the figures in which

FIG. 1 shows a first embodiment of a respiratory aid system according to the invention,

FIG. 2 shows one embodiment of a respiration detector and a ventilator according to the invention,

FIG. 3 shows a second embodiment of a respiratory aid system according to the invention,

FIG. 4 shows a third embodiment of a respiratory aid system according to the invention,

FIG. 5 shows a fourth embodiment of a respiratory aid system according to the invention, and

FIG. 6 shows a fifth embodiment of a respiratory aid system according to the invention.

FIG. 1 shows a patient 2 on a cot 4. The patient 2 is connected to a ventilator 6 by a tubing system 8 in order to receive respiratory aid from the ventilator 6. In principle, the ventilator 6 can be a known ventilator, such as the Servo Ventilator 300, Siemens-Elema AB, Sweden, or some other known respirator (including home-care breathing aid, CPAP-machines, resuscitation machines etc.) or anaesthetic machine. In principle, respiratory aid can consist of any conventional respiratory assistance given to patients who have or stand a risk of getting difficulty in achieving or are unable to achieve adequate spontaneous respiration.

A respiration detector 10 is connected to the ventilator 6 and, via a signal line 12, to the patient's 2 phrenic nerve. Here, the signal line 12 can be transcutaneously connected to the phrenic nerve or indirectly connected to the phrenic nerve from the surface of the skin. Neuroelectrical control signals for respiration, generated in the respiratory centre of the medulla oblongata, are carried along the phrenic nerve to the diaphragm (in particular). These signals are picked up by the signal line 12 and sent to the respiration detector 10.

The respiration detector 10 extracts the relevant signals related to respiration. Identification can be made using known signal processing methods. Signals concerning respiration or, the function of the diaphragm in this case, usually arrive as a train of impulses. The respiration detector 10 then generates a control signal, sent to the ventilator 6, according to respiration signals detected. More advanced analysis of the nerve impulses can be made with more advanced methods, inter alia including pattern recognition systems and artificial neural networks (ANN).

These respiratory signals are the earliest indication that the patient 2 wants to breathe. These signals can also supply information on the patient's 2 physiological need to breathe. The latter is in particular valid for patients 2 whose inability to breathe sufficiently is unrelated to injuries to or some impact on the respiratory centre.

One advantage of obtaining the respiratory signal at an early stage is that the respiratory aid (provided by a ventilator 6 in this instance) can be supplied according to the patient's 2 true physiological needs and not according to estimated needs or needs calculated in some other way. Moreover, respiration will have the most natural rhythm for the patient

2. So the triggering of inspiration phases is an essential part of the invention, but the neurological signals contain more intelligence than just information on when the patient should take a breath. In principle, they contain all the information essential to each individual breath, especially respiratory depth, inspiration duration and any inspiration pause. Some physiological respiratory control also concerns expirations, even if expiration is a normally passive process occurring when the respiratory musculature relaxes.

Since an inspiration phase can be started in synchrony with the patient's 2 own inspiration, breathing effort can be greatly reduced for patients 2 retaining some ability to breathe spontaneously.

A respiratory sensor can be used in parallel with patients 2 with a greater ability to breathe spontaneously so the control signal from the respiration detector 10 can be inhibited. This is illustrated in FIG. 2 in which the ventilator 6 and respiration detector 10 are depicted in greater detail.

The respiration detector 10 is connected to the patient 2 by an electrode 18 for sensing the neuroelectrical signals. Sensed signals are sent to a signal processing unit 20 for filtration and amplification in some suitable fashion. The processed signals are then sent to an analyser 22 for signal identification. Appropriate signal analysis can establish when the patient 2 wishes to breathe spontaneously and the extent to which the patient 2 wishes to breathe. Respiratory signals mainly consist of a train of impulses to the respiratory musculature (especially to the diaphragm in this example, since the phrenic nerve is being sensed).

Information on the presence of respiratory signals is sent to a signal generator 24 that generates a control signal

depending on the respiratory signals identified. This control signal is sent via a control line 26 to a control unit 28 in the ventilator 6.

The control unit 28 regulates the ventilator 6 according to parameters set by a physician and parameters measured by the ventilator 6.

A breathing gas is mixed to the right composition, pressure and flow in a valve unit 30. Different gases can be connected in the known fashion via a first gas connector 32A and a second gas connector 32B.

Measurement of pressure and flow can be performed in different parts of the system by a first flow meter 34, a first pressure meter 36, a second flow meter 38, a second pressure meter 40, a third flow meter 42 and a third pressure meter 44. When pressure and/or flow is/are measured, an initiated breath can be sensed as a change in pressure and/or flow. The control unit 28 plus one or more of the said meters thereby constitutes a respiration sensor. These meters are therefore only shown to illustrate that measurement of pressure and flow can be made at one or a plurality of locations in the system.

If the patient 2 commences a breath by drawing in air, the control signal's effect on the control device 28 is reduced, delayed or inhibited. A sufficiently strong spontaneous breath within a specific period of time after the respiration detector 10 senses a respiratory signal means that the patient 2 does not need respiratory aid during that breath, other than a supply of breathing gas. In these circumstances, the ventilator 6 can operate as a normal ventilator 6 and support the patient 2 according to a pre-determined pattern or according to the strength of the patient's 2 spontaneous breathing.

In principle, the respiration detector 10 can also sense when the patient 2 wishes to exhale and then send a signal to the ventilator 6 to permit the start of an exhalation (expiration). This spares the patient 2 the inconvenience of actively building up enough pressure in the lungs to activate the expiratory phase. During expiration, an expiratory valve 46 can be regulated to maintain an appropriate positive end expiratory pressure (PEEP) for the patient 2.

FIG. 3 shows an alternative design for the respiratory aid system according to the invention. A patient 2 placed on a cot 4 is connected to a respiration detector 10 by an electrode line 12. In this instance, the electrode line 12 is devised to sense signals in the respiratory centre itself or in nerve pathways that mainly carry respiratory signals to the respiratory musculature around the thorax.

A myostimulation device 14 is connected to the patient's 2 musculature at the diaphragm via a stimulation line 16 in order to stimulate the diaphragm's muscles with electrical signals and accordingly induce an inspiration.

Alternately, as shown in FIG. 4, a nerve stimulating device 48 can be used for stimulating the respiratory nerves via a stimulation line 50. In this instance the phrenic nerve is stimulated. This can be used in cases where there is a fault in the nervous system which prevents a natural passage of impulses from the respiratory centre to the muscle. A nerve stimulation "downstream" the fault can then maintain as normal respiration as possible. In the alternative, the impulses can be enhanced by superimposing the stimulation signal from the nerve stimulating device 48.

FIG. 5 shows another alternative, where a magnetic stimulation device 52 is arranged over the lung region of the

patient 2 for magnetic stimulation of the respiratory system. The magnetic stimulation device 52 is controlled and powered by a control unit 54 via a line (or set of lines) 56. In the specific embodiment of FIG. 5, the nerve impulses of the patient 2 are detected at several places via a multitude of electrodes 12.

Finally, FIG. 6 shows another alternative, where a casing 58 placed around the upper part of the patient 2 provides the respiratory aid. Pressure generated by the casing 58 is controlled and supplied by control unit 60 via pressure line 62.

The respiratory aid devices and nerve impulse detection devices shown in the embodiments can be combined where suitable. For instance, a multitude of sensing electrodes (FIG. 5) can be used to sense the nerve impulses in the embodiment showing a ventilator (FIG. 1).

Claims

1. A respiratory aid system (6, 8, 10, 12; 10, 12, 14, 16; 10, 12, 48, 50; 10, 12, 52, 54, 56; 10, 12, 58, 60, 62) comprising a device (6; 14; 48; 52, 54; 58, 60, 62) arranged for connection to a living creature (2) in order to facilitate, support and/or control the breathing of the living creature (2), characterised by a sensor means (18) devised to pick up neuroelectrical signals (nerve impulses) from the living creature (2), an analyser (20, 22) for identifying signals related to respiration from the recorded neuroelectrical signals and a signal generator (24), connected to the analyser (20, 22), for generating and sending a control signal, related to the identified signals, to the device (6; 14; 48; 52, 54; 58, 60, 62).

2. The respiratory aid system according to claim 1, characterised in that the sensor means (18) is devised to pick up neuroelectrical signals from the respiratory centre or from any nerve connecting the respiratory centre with respiratory musculature, in particular the phrenic nerve.

3, The respiratory aid system according to claim 1 or 2, characterised in that the device (6) is a ventilator devised to trigger an inspiration phase by generating a flow of a breathing gas in response to the control signal transmitted by the signal generator (24).

4. The respiratory aid system according to claim 1 or 2, characterised in that the device (14) is a myostimulator devised to trigger an inspiration phase by generating and emitting a myostimulation signal in response to the control signal transmitted by the signal generator (24).

5. The respiratory aid system according to claim 1 or 2, characterised in that the device (48) is a nerve stimulator devised to trigger an inspiration phase by generating and emitting a nerve stimulation signal in response to the control signal transmitted by the signal generator (24).

6. The respiratory aid system according to claim 1 or 2, characterised in that the device (52, 54) is a magnetic stimulator devised to trigger an inspiration phase by generating and emitting a magnetic stimulation signal in response to the control signal transmitted by the signal generator (24).

7. The respiratory aid system according to claim 1 or 2, characterised in that the device (58, 60, 62) is a chamber respirator devised to trigger an inspiration phase by generating a pressure variation on an enclosed part of the patient's body in response to the control signal transmitted by the signal generator (24).

8. The respiratory aid system according to any of the above claims, characterised by a respiration sensor (28, 34, 36, 38, 40, 42, 44, 46), devised to detect spontaneous respiration by the living creature, said respiration sensor (28, 34, 36, 38, 40, 42, 44, 46) generating a detection signal when spontaneous breathing is sensed.

9. The respiratory aid system according to claim 8, characterised in that the respiration sensor (28, 34, 36, 38, 40, 42, 44, 46) is devised to determine the magnitude of spontaneous breathing and include the information on the magnitude of spontaneous breathing in the detection signal and that the device (6; 14; 48; 52, 54; 58, 60, 62) is adapted to trigger the inspiration phase according to the magnitude of spontaneous breathing.

10. A respiratory aid system (6, 8, 10, 12; 10, 12, 14, 16; 10, 12, 48, 50; 10, 12, 52, 54, 56; 10, 12, 58, 60, 62), intended for use with a method for physiologically adapted respiratory aid for a living creature (2), characterised by a device (10, 12) for sensing the respiration-related part of the living creature's (2) nervous system and generating a control signal when it senses a physiological attempt at breathing by the living creature (2) and by a device (6; 14; 48; 52, 54; 58, 60, 62) for generating respiratory aid according to the control signal.

11. The respiratory aid system according to claim 10, characterised in that the device (6; 14; 48; 52, 54; 58, 60, 62) generates respiratory aid in the form of a flow of gas and/or a myostimulation and/or a nerve stimulation signal and/or a magnetic stimulation signal and/or a mechanic stimulation of the thoratic region.

12. The respiratory aid system according to claim 10 or 11, characterised in that a response sensor (28, 34, 36, 38, 40, 42, 44, 46) is devised to sense the living creature's (2) response to the physiological attempt at respiration, generate a detection signal and send this signal to the device (6; 14; 48; 52, 54; 58, 60, 62) which is devised to adapt respiratory aid according to the detection signal.

13. A respiration detector (10) for identifying physiological attempts at respiration by the living creature (2), characterised by a device (12, 18, 20, 22) adapted to sense the respiration-related part of the living creature's (2) nervous system and generate an identification signal when it senses a physiological attempt at respiration by the living creature (2).

14. A method for identifying physiological attempts at respiration by the living creature, characterised by the

picking up neuroelectrical signals (nerve impulses) originating in the respiratory centre of the living creature;

filtering out of signal components related to respiration; and

identification of respiratory signals related to the attempts at respiration.

15. The method according to claim 14, characterised in that a triggering signal is generated according to the respiratory signals identified.

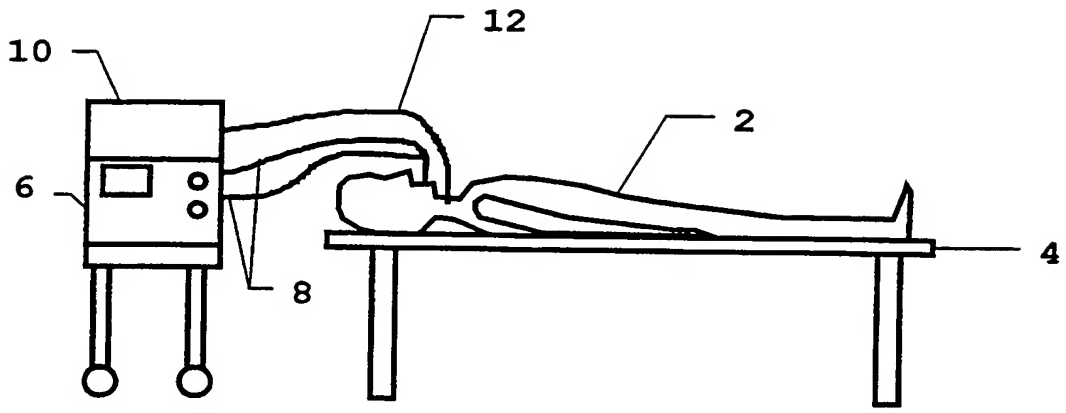

FIG. 1

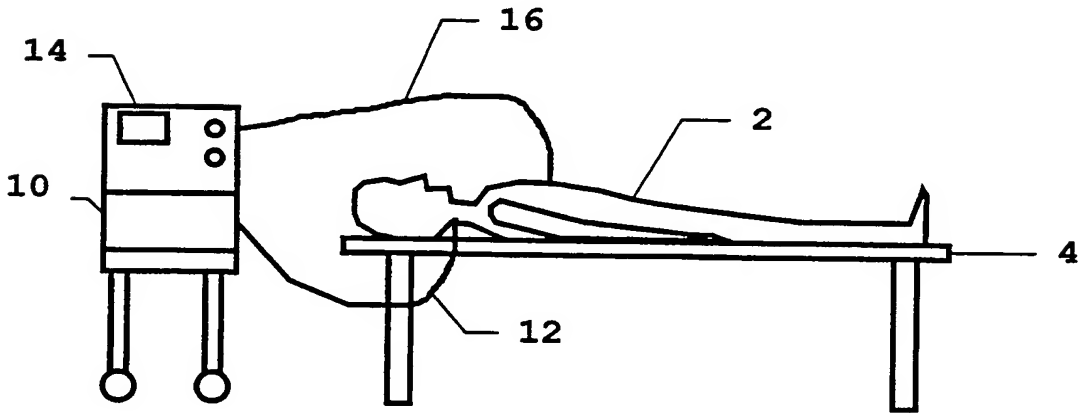

FIG. 3

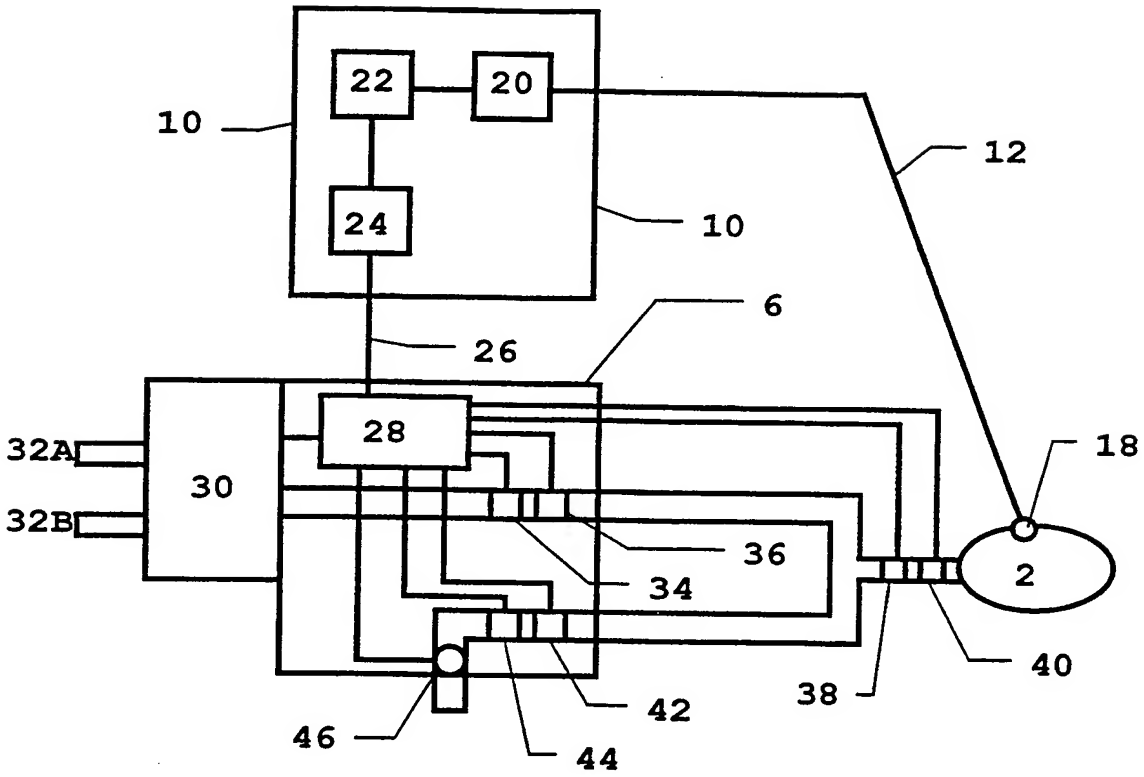

FIG. 2

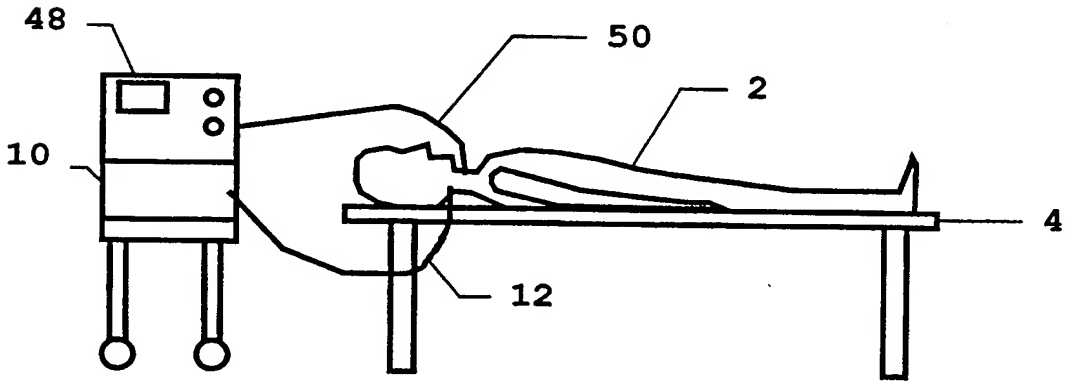

FIG. 4

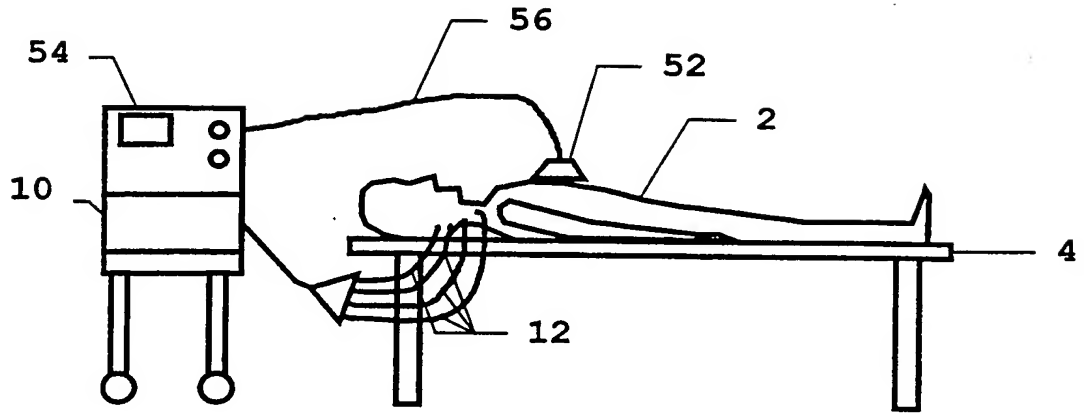

FIG. 5

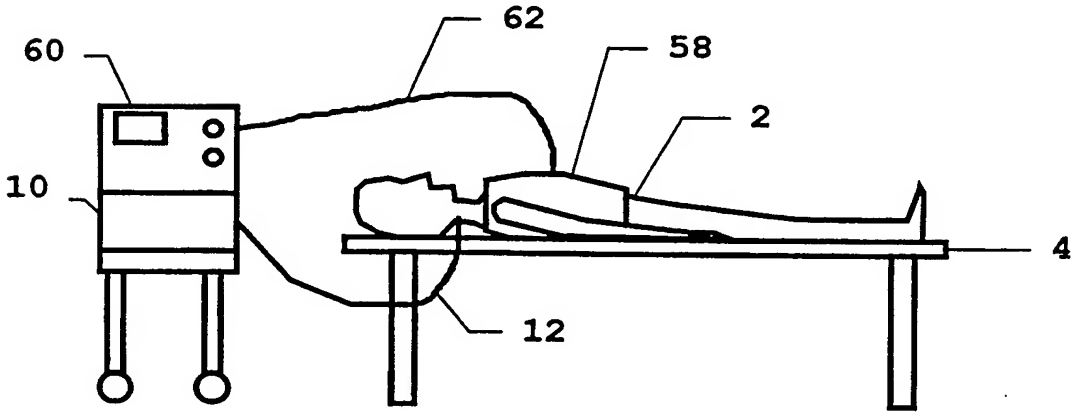

FIG. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 99/01022

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 16/00, A61N 1/36, A61B 5/08
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61M, A61N, A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0702977 A2 (R.L.TESTERMAN), 27 March 1996 (27.03.96), column 5, line 32 - column 8, line 6, figure 5	1-15
A	EP 0811394 A1 (SIEMENS AKTIENGESELLSCHAFT), 10 December 1997 (10.12.97), column 1, line 3 - line 11; column 1, line 47 - line 2; column 3, figure 2	3
D,Y	US 5056519 A (D.J.VINCE), 15 October 1991 (15.10.91), column 3, line 21 - line 35, figure 1	4-12,14-15

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
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"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 October 1999	03 -11- 1999
Name and mailing address of the ISA/ Swedish Patent Offic Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Patrik Blidefalk Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 99/01022

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
D,A	WO 9301862 A1 (CYBERONICS,INC.), 4 February 1993 (04.02.93), figure 2, abstract -- --------	1-15

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE99/01022

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 14 - 15
because they relate to subject matter not required to be searched by this Authority, namely:

A diagnostic method practised on the human or animal body. PCT - Rule 39.1(iv). Nevertheless, a search has been executed for these claims. The search has been based on the alleged effects of the composition.

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

28/09/99

International application No.
PCT/SE 99/01022

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